

Senate File 453 - Introduced

SENATE FILE 453
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO SSB 1021)

A BILL FOR

1 An Act relating to the board of pharmacy, including nonresident
2 pharmacy and outsourcing facility licensure, pharmacist
3 supervision of pharmacy technicians, alternate board
4 members, and enforcement authority.
5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. Section 147.107, subsection 2, paragraph a, Code
2 2015, is amended to read as follows:

3 a. A pharmacist, physician, dentist, or podiatric physician
4 who dispenses prescription drugs, including but not limited
5 to controlled substances, for human use, may delegate
6 nonjudgmental dispensing functions to staff assistants only
7 when verification of the accuracy and completeness of the
8 dispensing is determined by the pharmacist or practitioner
9 in the pharmacist's or practitioner's physical presence.
10 However, the physical presence requirement does not apply
11 when a pharmacist or practitioner is utilizing an automated
12 dispensing system; ~~or~~ when a pharmacist is utilizing a
13 tech-check-tech program, as defined in section 155A.3; or when
14 a pharmacist is remotely supervising a certified pharmacy
15 technician practicing at a telepharmacy site approved by the
16 board of pharmacy. When using an automated dispensing system
17 the pharmacist or practitioner shall utilize an internal
18 quality control assurance plan that ensures accuracy for
19 dispensing. When using a tech-check-tech program or when
20 remotely supervising a certified pharmacy technician practicing
21 at an approved telepharmacy site, the pharmacist shall utilize
22 an internal quality control assurance plan, in accordance
23 with rules adopted by the board of pharmacy, that ensures
24 accuracy for dispensing. Verification of automated dispensing,
25 ~~and tech-check-tech,~~ and telepharmacy practice accuracy and
26 completeness remains the responsibility of the pharmacist or
27 practitioner and shall be determined in accordance with rules
28 adopted by the board of pharmacy, the board of medicine, the
29 dental board, and the board of podiatry for their respective
30 licensees.

31 Sec. 2. Section 155A.3, Code 2015, is amended by adding the
32 following new subsection:

33 NEW SUBSECTION. 40A. "Telepharmacy" means the practice of
34 pharmacy via telecommunications as provided by the board by
35 rule.

1 Sec. 3. Section 155A.13A, Code 2015, is amended to read as
2 follows:

3 **155A.13A Nonresident pharmacy license — required, renewal,
4 discipline.**

5 1. *License required.* A pharmacy located outside of this
6 state ~~which~~ that delivers, dispenses, or distributes by any
7 method, prescription drugs or devices to an ultimate user in
8 this state shall obtain a nonresident pharmacy license from
9 the board. The board shall make available an application form
10 for a nonresident pharmacy license and shall require such
11 information it deems necessary to fulfill the purposes of this
12 section. A nonresident pharmacy shall do all of the following
13 in order to obtain a nonresident pharmacy license from the
14 board:

15 a. Submit a completed application form and an application
16 fee as determined by the board.

17 b. Submit evidence of possession of a valid pharmacy
18 license, permit, or registration ~~as a pharmacy in compliance~~
19 ~~with the laws of the state in which it is located, a copy of~~
20 ~~the most recent inspection report resulting from an inspection~~
21 ~~conducted by the regulatory or licensing agency of the state~~
22 ~~in which it is located, and evidence of compliance with all~~
23 ~~legal directions and requests for information issued by the~~
24 ~~regulatory or licensing agency of the state in which it is~~
25 ~~located~~ issued by the home state licensing authority.

26 c. (1) Submit a list of the names, titles, and locations of
27 all principal owners, partners, or officers of the nonresident
28 pharmacy, all pharmacists employed by the nonresident pharmacy
29 who deliver, dispense, or distribute by any method prescription
30 drugs to an ultimate user in this state, and of the pharmacist
31 in charge of the nonresident pharmacy. A nonresident pharmacy
32 shall update the list within thirty days of any addition,
33 deletion, or other change to the list. Submit an inspection
34 report that satisfies all of the following requirements:

35 (a) Less than two years have passed since the date of

1 inspection.

2 (b) The inspection occurred while the pharmacy was in
3 operation. An inspection prior to the initial opening of the
4 pharmacy shall not satisfy this requirement.

5 (c) The inspection report addresses all aspects of the
6 pharmacy's business that will be utilized in Iowa.

7 (d) The inspection was performed by or on behalf of the home
8 state licensing authority, if available.

9 (e) The inspection report is the most recent report
10 available that satisfies the requirements of this paragraph
11 "c".

12 (2) If the home state licensing authority has not conducted
13 an inspection satisfying the requirements of this paragraph
14 "c", the pharmacy may submit an inspection report from the
15 national association of boards of pharmacy's verified pharmacy
16 program, or the pharmacy may submit an inspection report from
17 another qualified entity if preapproved by the board, if the
18 inspection report satisfies all of the other requirements of
19 this paragraph "c".

20 (3) The board may recover from a nonresident pharmacy, prior
21 to the issuance of a license or renewal, the costs associated
22 with conducting an inspection by or on behalf of the board
23 for purposes of satisfying the requirement in subparagraph
24 (1), subparagraph division (d). In addition, the nonresident
25 pharmacy shall submit evidence of corrective actions for all
26 deficiencies noted in the inspection report and shall submit
27 evidence of compliance with all legal directives of the home
28 state regulatory or licensing authority.

29 d. Submit evidence that the nonresident pharmacy maintains
30 records of the controlled substances delivered, dispensed, or
31 distributed to ultimate users in this state.

32 e. Submit evidence that the nonresident pharmacy provides,
33 during its regular hours of operation for at least six days
34 and for at least forty hours per week, a toll-free telephone
35 service to facilitate communication between ultimate users in

1 ~~this state and~~, the telephone number of which is printed on the
 2 label affixed to each prescription dispensed or distributed
 3 in Iowa, that allows patients to speak with a pharmacist who
 4 has access to the ultimate user's patient records in the
 5 nonresident pharmacy, and that the toll-free number is printed
 6 on the label affixed to each container of prescription drugs
 7 delivered, dispensed, or distributed in this state at least six
 8 days per week for a total of at least forty hours.

9 2. Pharmacist license requirement. The pharmacist who is
 10 the pharmacist in charge of the nonresident pharmacy shall
 11 be designated as such on the nonresident pharmacy license
 12 application or renewal. Any change in the pharmacist in charge
 13 shall be reported to the board within ten days of the change.
 14 The pharmacist in charge must be registered, not licensed,
 15 according to rules established by the board of pharmacy.

16 ~~2.~~ 3. License renewal. A nonresident pharmacy shall renew
 17 its license on or before January 1 annually. In order to renew
 18 a nonresident pharmacy license, a nonresident pharmacy shall
 19 submit a ~~renewal~~ completed application and fee as determined
 20 by the board, and shall fulfill all of the requirements of
 21 subsection 1, ~~paragraphs "b" through "e"~~. A nonresident
 22 pharmacy shall pay an additional fee for late renewal as
 23 determined by the board.

24 4. License denial. The board shall refuse to issue
 25 a nonresident pharmacy license for failure to meet the
 26 requirements of subsection 1. The board may refuse to issue
 27 or renew a license for any grounds under which the board
 28 may impose discipline. License or renewal denials shall be
 29 considered contested cases governed by chapter 17A.

30 ~~3.~~ 5. Discipline. The board may ~~deny~~ fine, suspend, or
 31 revoke, or impose other disciplinary sanctions on a nonresident
 32 pharmacy license for any violation of this section, section
 33 155A.15, subsection 2, paragraph "a", "b", "d", "e", "f", "g",
 34 "h", or "i", chapter 124, 124A, 124B, 126, or 205, or a rule of
 35 the board. of the following:

1 a. Any violation of the federal Food, Drug, and Cosmetic Act
2 or federal regulations promulgated under the Act. A warning
3 letter issued by the United States food and drug administration
4 shall be conclusive evidence of a violation.

5 b. Any conviction of a crime related to prescription drugs
6 or the practice of pharmacy committed by the nonresident
7 pharmacy, pharmacist in charge, or individual owner, or if the
8 pharmacy is an association, joint stock company, partnership,
9 or corporation, by any managing officer.

10 c. Refusing access to the pharmacy or pharmacy records to an
11 agent of the board for the purpose of conducting an inspection
12 or investigation.

13 d. Any violation of this chapter or chapter 124, 124A, 124B,
14 126, or 205, or rule of the board.

15 **Sec. 4. NEW SECTION. 155A.13C Outsourcing facility license**
16 **— renewal, cancellation, denial, discipline.**

17 1. *License required.* Any compounding facility that is
18 registered as an outsourcing facility, as defined in 21
19 U.S.C. §353b, that distributes sterile compounded human
20 drug products without a patient-specific prescription to an
21 authorized agent or practitioner in this state shall obtain an
22 outsourcing facility license from the board prior to engaging
23 in such distribution. If an outsourcing facility dispenses
24 prescription drugs pursuant to patient-specific prescriptions
25 to patients in Iowa, the outsourcing facility shall obtain and
26 maintain a valid Iowa pharmacy license or Iowa nonresident
27 pharmacy license under this chapter. The board shall make
28 available an application form for an outsourcing facility
29 license and shall require such information it deems necessary
30 to fulfill the purposes of this section. An outsourcing
31 facility shall do all of the following in order to obtain an
32 outsourcing facility license from the board:

33 a. Submit a completed application form and application fee
34 as determined by the board.

35 b. Submit evidence of possession of a valid registration as

1 an outsourcing facility with the United States food and drug
2 administration.

3 *c.* If one or more inspections have been conducted by the
4 United States food and drug administration in the five-year
5 period immediately preceding the application, submit a copy
6 of any correspondence from the United States food and drug
7 administration as a result of the inspection, including but
8 not limited to any form 483s, warning letters, or formal
9 responses, and all correspondence from the applicant to the
10 United States food and drug administration related to such
11 inspections, including but not limited to formal responses and
12 corrective action plans. In addition, the applicant shall
13 submit evidence of correction of all deficiencies discovered in
14 such inspections and evidence of compliance with all directives
15 from the United States food and drug administration.

16 *d.* Submit evidence that the supervising pharmacist, as
17 described in 21 U.S.C. §353b(a), holds a valid pharmacist
18 license in the state in which the facility is located and that
19 such license is in good standing.

20 2. *License renewal.* An outsourcing facility shall renew
21 its license on or before January 1 annually. In order to renew
22 an outsourcing facility license, an outsourcing facility shall
23 submit a completed application and fee as determined by the
24 board, and shall fulfill all of the requirements of subsection
25 1. An outsourcing facility shall pay an additional fee for
26 late renewal as determined by the board.

27 3. *License cancellation.* If a facility ceases to be
28 registered as an outsourcing facility with the United States
29 food and drug administration, the facility shall notify the
30 board in writing and shall surrender its Iowa outsourcing
31 facility license to the board within thirty days of such
32 occurrence. Upon receipt, the board shall administratively
33 cancel the outsourcing facility license.

34 4. *License denial.* The board shall refuse to issue
35 an outsourcing facility license for failure to meet the

1 requirements of subsection 1. The board may refuse to issue
2 or renew a license for any grounds under which the board
3 may impose discipline. License or renewal denials shall be
4 considered contested cases governed by chapter 17A.

5 5. *Discipline.* The board may fine, suspend, revoke, or
6 impose other disciplinary sanctions on an outsourcing facility
7 license for any of the following:

8 a. Any violation of the federal Food, Drug, and Cosmetic Act
9 or federal regulations promulgated under the Act. A warning
10 letter issued by the United States food and drug administration
11 shall be conclusive evidence of a violation.

12 b. Any conviction of a crime related to prescription drugs
13 or the practice of pharmacy committed by the outsourcing
14 facility, supervising pharmacist, or individual owner, or
15 if the outsourcing facility is an association, joint stock
16 company, partnership, or corporation, by any managing officer.

17 c. Refusing access to the outsourcing facility or facility
18 records to an agent of the board for the purpose of conducting
19 an inspection or investigation.

20 d. Any violation of this chapter or chapter 124, 124A, 124B,
21 126, or 205, or rule of the board.

22 Sec. 5. Section 155A.26, subsections 2, 3, and 4, Code 2015,
23 are amended to read as follows:

24 2. Make audits of the supply and inventory of controlled
25 substances and prescription drugs in the possession of any and
26 all individuals or institutions authorized to have possession
27 of any controlled substances or prescription drugs, regardless
28 of the location of the individual or institution.

29 3. Conduct routine and unannounced inspections of
30 pharmacies, drug wholesalers, and the offices or business
31 locations of all individuals and institutions authorized to
32 have possession of prescription drugs including controlled
33 substances or prescription devices, regardless of the location
34 of the office or business.

35 4. Conduct inspections and investigations related to the

1 practice of pharmacy and the distribution of prescription drugs
2 and devices in and into this state.

3 Sec. 6. Section 155A.33, Code 2015, is amended to read as
4 follows:

5 **155A.33 Delegation of technical functions.**

6 A pharmacist may delegate technical dispensing functions
7 to pharmacy technicians, but only if the pharmacist is
8 physically present to verify the accuracy and completeness
9 of the patient's prescription prior to the delivery of the
10 prescription to the patient or the patient's representative.
11 However, the physical presence requirement does not apply when
12 a pharmacist is utilizing an automated dispensing system or
13 a tech-check-tech program or when a pharmacist is remotely
14 supervising a certified pharmacy technician practicing at
15 a telepharmacy site approved by the board. When using an
16 automated dispensing system or a tech-check-tech program, or
17 when remotely supervising a certified pharmacy technician
18 practicing at an approved telepharmacy site, the pharmacist
19 shall utilize an internal quality control assurance plan that
20 ensures accuracy for dispensing. Verification of automated
21 dispensing, and tech-check-tech, and telepharmacy practice
22 accuracy and completeness remains the responsibility of the
23 pharmacist and shall be determined in accordance with rules
24 adopted by the board.

25 Sec. 7. NEW SECTION. **155A.45 Inspection reports —**
26 **disclosure.**

27 Notwithstanding section 272C.6, subsection 4, paragraph "a",
28 an inspection report in possession of the board, regardless
29 of whether the report is based on a routine inspection or an
30 inspection prompted by one or more complaints, may be disclosed
31 to the national association of boards of pharmacy's inspection
32 network.

33

EXPLANATION

34 The inclusion of this explanation does not constitute agreement with
35 the explanation's substance by the members of the general assembly.

1 This bill relates to the operation of, and persons and
2 activities regulated by, the board of pharmacy.

3 The bill provides for remote pharmacist supervision of
4 a certified pharmacy technician practicing at an approved
5 telepharmacy practice site, pursuant to rules of the board.

6 The bill defines the term "telepharmacy" as it relates to the
7 practice of pharmacy.

8 The bill amends provisions relating to the licensure of
9 nonresident pharmacies that provide prescription pharmaceutical
10 products to patients located in Iowa. The bill requires the
11 pharmacist in charge of a nonresident pharmacy to be identified
12 as such on the nonresident pharmacy license application or
13 renewal, report any change in the pharmacist in charge to the
14 board within 10 days, and be registered in accordance with
15 board rules. The bill clarifies the information required for
16 license application, including evidence of recent inspection
17 of the pharmacy and defining the elements of an acceptable
18 inspection. The bill describes and identifies various entities
19 that may be employed to perform an inspection acceptable for
20 Iowa licensure. The bill authorizes the board to recoup from
21 a nonresident pharmacy any costs incurred by the board in
22 completing an inspection of the nonresident pharmacy if the
23 nonresident pharmacy cannot provide an acceptable inspection
24 report.

25 The bill eliminates the requirement that a nonresident
26 pharmacy maintain minimum hours and days of operation,
27 requiring in lieu thereof that a pharmacist with access to
28 patient records be readily available to speak to patients via
29 a toll-free telephone number at least six days per week for a
30 total of at least 40 hours.

31 The bill authorizes the board to deny an application for a
32 nonresident pharmacy license if the applicant fails to meet the
33 application requirements and authorizes the board to refuse to
34 issue or renew a nonresident pharmacy license for any grounds
35 under which the board may impose discipline.

1 The bill amends the grounds for disciplining nonresident
2 pharmacies. The board may impose discipline for any violation
3 of the federal Food, Drug, and Cosmetic Act or regulations
4 promulgated under the Act including the issuance by the United
5 States food and drug administration of a warning letter;
6 conviction of a crime related to prescription drugs or the
7 practice of pharmacy by the owner, managing officer, or the
8 pharmacy; refusal to provide the board's agent access to the
9 pharmacy or pharmacy records for purposes of inspection or
10 investigation; and any violation of Iowa law or rule of the
11 board relating to the practice of pharmacy and the distribution
12 of prescription products in Iowa. For nonresident pharmacies,
13 the bill adds that the board has the option to fine the
14 nonresident pharmacy, in addition to license suspension,
15 revocation, and other sanctions.

16 The bill adds a new license classification for outsourcing
17 facilities, for the purpose of licensing and regulating any
18 compounding facility that is registered under federal law as an
19 outsourcing facility. The bill establishes the requirements
20 for application and licensure; license renewal, cancellation,
21 and denial; and establishes grounds for discipline of the
22 outsourcing facility license identical to the disciplinary
23 procedure available regarding nonresident pharmacies.

24 The bill clarifies that the officers, agents, inspectors,
25 and representatives of the board may perform functions and
26 activities relating to authorized enforcement activities
27 regardless of the location of the office or business that is
28 the subject of the enforcement activities. The bill authorizes
29 the board to provide reports of inspections of board licensees
30 to the national association of boards of pharmacy's inspection
31 network, a closed network of information regarding individual
32 states' licensees that compiles information and makes that
33 information available to other state boards of pharmacy for
34 purposes of regulating the subject licensees.